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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,510	03/06/2001	Brett Cowan	3652-33	1367

23117 7590 06/16/2005

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EXAMINER

LU, TOM Y

ART UNIT	PAPER NUMBER
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2621

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,510

Applicant(s)

COWAN ET AL.

Examiner

Tom Y. Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-41, 43-53, 55-65 and 67-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-41, 43-53, 55-65 and 67-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Request for Continued Examination filed on 6/2/2005 has been entered.
2. Upon entry of the Request for Continued Examination, the amendment filed on 1/16/2005 has been entered.
3. Claims 1-37, 42, 54, 66 and 75-81 have been cancelled.
4. Claims 38-41, 43-53, 55-65 and 67-74 are pending.

Response to Arguments

5. Applicant's arguments filed on 1/16/2005 have been fully considered but they are not persuasive.

The Sheehan reference:

Applicant argues the Sheehan reference fails to teach the limitation of “displaying to a user a user-selected image of the subject organ or part thereof; displaying to the user a representation of the initial fit of the reference model by superimposing on the user-selected image a representation of the intersection of the reference model with the plane of the user-selected image”. Upon further review of specification, and in light of applicant’s arguments, the examiner respectfully disagrees as follows: Sheehan teaches manually selecting an imaging plane for tracing at column 13, line 28-29. Also, it is understood by the examiner that the imaging planes must be displayed to the user before the selection can be taken place. Therefore, the limitation of “displaying to a user a user selected image of the subject organ” is fully satisfied. Additionally, Sheehan teaches intersecting the mesh model with imaging plane 222 to obtain a predicted image 226. It is understood by the examiner the imaging plane 222 is user-selected as explained above, and the predicted image 226 is the claimed “a representation of the intersection of the reference model”, column 14, lines 64-66, and figure 12

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displaying the fitting of the model and the imaging plane 222. Moreover, the superimposing function is interpreted by the examiner as matching between the imaging plane 222 and the predicted 226 for further refinement of the model, column 16, lines 42-43.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 38-41, 43-53, 55-65 and 67-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Sheehan et al (U.S. Patent No. 6,106,466).

- a. Referring to Claim 38, Sheehan discloses defining the spatial position of at least two of the images (Sheehan at column 8, lines 64-66, teaches “the time varying position and orientation of the ultrasound transducer relative to magnetic field generator 68 comprise data that are stored in a non-volatile memory”, such position data is spatial position data, which defines the position of the ultrasound transducer at the time each image frame is recorded by the CPU and thereby enable the CPU to compute the three-dimensional coordinates, column 9, lines 3-7); forming an initial fit between a reference model (Sheehan at column 12, line 9, discloses a mesh model of an archetype heart, which is the claimed “reference model”. Note Sheehan at column 13, line 3-6, teaches abstract mesh model is used for initial fitting) of the geometric shape of the organ or part thereof and the images according to reference markers on the

images (column 13, lines 8-9, anatomic landmarks are the claimed “reference markers”); displaying to a user a user-selected image of the subject organ or part thereof (Sheehan teaches manually selecting an imaging plane for tracing at column 13, line 28-29); displaying to the user a representation of the initial fit of the reference model by superimposing on the user-selected image a representation of the intersection of the reference model with the plane of the user-selected image (Sheehan teaches intersecting the mesh model with imaging plane 222 to obtain a predicted image 226. It is understood by the examiner the imaging plane 222 is user-selected as explained above, and the predicted image 226 is the claimed “a representation of the intersection of the reference model”, column 14, lines 64-66, and figure 12 displaying the fitting of the model and the imaging plane 222. Moreover, the superimposing function is interpreted by the examiner as matching between the imaging plane 222 and the predicted 226 for further refinement of the model, column 16, lines 42-43.); manually user-defining one or more reference guide points associated with the image displayed to the user, for which the spatial positions have been defined; converting the guide points to three-dimensional coordinates (Sheehan at column 11, lines 63-67, column 12, lines 1-2, teaches points of landmarks or structures are converted from x,y coordinates to x,y,z coordinates. Note points of landmarks or structures on observed images are the claimed “reference guide points”); improving the fit of the model by fitting the model to the guide points to form an estimate model for the organ or part (Sheehan at column 12, lines 53-61, teaches by reiteratively repositioning the control vertices or points to smooth the model to achieve the best fit. Note such control vertices are in association with

anatomic landmarks. And these control vertices or points are the claimed “guide points”. Also see column 13, lines 11-12); and assessing the one or more characteristic from the estimate model (the claimed “characteristics” herein are ventricular volume, mass, and function, ejection fraction, wall thickening, etc, column 17, lines 45-47).

- b. Referring to Claim 39, Sheehan discloses forming the initial fit between the reference model and the images by defining a point on each of two images, defining a reference line in 3-dimensional space between the point, calculating the distance as a function of the length of the reference line, and at least approximately matching the scale of the reference model and the images according to the distance between the points (Sheehan in figure 13, block 230, teaches mesh model rigidly aligned and scaled to match image data at 3 landmark points, and see the central axis in figure 6 for so-called “reference line”).
- c. Referring to Claim 40, Sheehan discloses wherein the reference model comprises a mathematically defined reference model (Sheehan at column 12, lines 8-11, teaches the reference model is a mathematically defined reference model).
- d. Referring to Claim 41, Sheehan discloses wherein the reference model comprises an ellipsoid having the reference line as a central axis and one or more surface points, each surface point specified by a radial distance from the central axis (see figure 6).
- e. Referring to Claim 43, Sheehan discloses the step of performing image processing on one or more of the images (column 14, lines 64-66).
- f. Referring to Claim 44, Sheehan discloses wherein the reference points are boundary points on the image (column 13, lines 25-28).

- g. Referring to Claim 45, Sheehan discloses the step of calculating the volume of the subject organ or part from the estimate model (column 17, lines 45-47).
- h. Referring to Claim 46, Sheehan discloses the step of calculating the mass of the subject organ or part from the estimate model (column 17, lines 45-47).
- i. Referring to Claim 47, Sheehan discloses wherein the subject organ comprises a ventricle of the heart and the characteristics measured include ventricular mass, endocardial volume and/or wall thickness of all of the ventricle or part thereof (column 17, lines 45-47).
- j. Referring to Claim 48, Sheehan discloses wherein the subject organ comprises a ventricle of the heart and the characteristics measured include ventricular abnormalities identified through changes in a wall thickness over time (Sheehan at abstract teaches the imaging processing is carried out over at least one cardiac cycle, which allows user to define any ventricular abnormalities identified through changes in wall thickness over time).
- k. Referring to Claim 49, Sheehan discloses wherein the subject organ comprises a kidney and the characteristics measured included cortical thickness (Sheehan at column 9, lines 35-36, teaches his system is applicable to other organs in the patient's body, and a kidney is an organ).
- l. With regard to Claim 50, all limitations are addressed in Claim 38.
- m. With regard to Claim 51, all limitations are addressed in Claim 39.
- n. With regard to Claim 52, all limitations are addressed in Claim 40.
- o. With regard to Claim 53, all limitations are addressed in Claim 41.
- p. With regard to Claim 55, all limitations are addressed in Claim 43.

- q. With regard to Claim 56, all limitations are addressed in Claim 44.
- r. With regard to Claim 57, all limitations are addressed in Claim 45.
- s. With regard to Claim 58, all limitations are addressed in Claim 46.
- t. With regard to Claim 59, all limitations are addressed in Claim 47.
- u. With regard to Claim 60, all limitations are addressed in Claim 48.
- v. With regard to Claim 61, all limitations are addressed in Claim 49.
- w. With regard to Claim 62, the only difference between Claim 62 and Claim 38 is
Claim 62 calls for a computer program, Sheehan at column 8, line 15, teaches a
software running on CPU 52 to carry out all the implementation steps.
- x. With regard to Claim 63, all limitations are addressed in Claim 39.
- y. With regard to Claim 64, all limitations are addressed in Claim 40.
- z. With regard to Claim 65, all limitations are addressed in Claim 41.
- aa. With regard to Claim 67, all limitations are addressed in Claim 43.
- bb. With regard to Claim 68, all limitations are addressed in Claim 44.
- cc. With regard to Claim 69, all limitations are addressed in Claim 45.
- dd. With regard to Claim 70, all limitations are addressed in Claim 46.
- ee. With regard to Claim 71, all limitations are addressed in Claim 47.
- ff. With regard to Claim 72, all limitations are addressed in Claim 48.
- gg. With regard to Claim 73, all limitations are addressed in Claim 49.
- hh. Referring to Claim 74, Sheen at column 8, line 68, discloses non-volatile memory
such as a hard drive, which is a computer readable medium.

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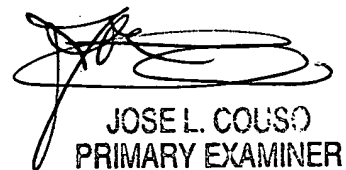
Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tom Y. Lu whose telephone number is (571) 272-7393. The examiner can normally be reached on 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Mancuso can be reached on (571)-272-7695. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tom Y. Lu


JOSE L. COUSO
PRIMARY EXAMINER